

Form PTO-1449 (modified)	Atty. Docket No.: <b>CHEP:015US</b>	Serial No.: <b>10/561,034</b>
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	Applicant: <b>Laurence CHRISTA <i>et al.</i></b>	
	Filing Date: <b>July 24, 2006</b>	Group: <b>1646</b>
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Pages 1-2</i>

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C4	"Comparison of short versus full length ALF-5755 activity on primary culture of rat hepatocytes," <i>INSERM</i> , Research Report of Dr. Didier Samuel, M.D., Ph.D., pages 1-7.
	C5	"Evaluation Report, Research Unit: Physiopathogenesis and treatment of fulminant hepatitis and liver cancer," <i>French Research and Education Evaluation Agency (AERES)</i> , 11 pages, December 2008.
	C6	"Guidance for industry – For the submission of chemistry, manufacturing, and controls information for a therapeutic recombinant DNA-derived product or a monoclonal antibody product for <i>in vivo</i> use," <i>Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER)</i> , August 1996.
	C7	"Guidance for industry – Q6B specifications: test procedures and acceptance criteria for biotechnological/biological products," <i>U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER)</i> , pages 1-21, August 1999.
	C8	"Guideline for industry – Quality of biotechnological products: stability testing of biotechnological/biological products," <i>Expert Working Group (Quality) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)</i> , pages 1-10, July 1996.
	C9	"Points to consider in the production and testing of new drugs and biologicals produced by recombinant DNA technology," <i>Office of Biologics Research and Review – Center for Drugs and Biologics</i> , Draft, April 10, 1985.

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EXAMINER: /Zachary Howard/

DATE CONSIDERED: 10/13/2010

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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Exam. Init.	Ref. Des.	Citation
	C10	"Production and quality control of medicinal products derived by recombinant DNA technology," <i>European Agency for the Evaluation of Medicinal Products (EMA)</i> , pages 205-216, December 1994.
	C11	"Quality of biotechnological products: stability testing of biotechnological/biological products," <i>European Agency for the Evaluation of Medicinal Products (EMA)</i> , pages 263-273, December 1995.
	C12	"Use of transgenic animals in the manufacture of biological medicinal products for human use," <i>European Agency for the Evaluation of Medicinal Products (EMA)</i> , pages 287-294, December 1994.
	C13	Christa <i>et al.</i> , "High expression of the human hepatocarcinoma-intestine-pancreas/pancreatic-associated protein (HIP/PAP) gene in the mammary gland of lactating transgenic mice – Secretion into the milk and purification of the HIP/PAP lectin," <i>Eur. J. Biochem.</i> , 267:1665-1671, 2000.

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